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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,718	07/01/2003	Weixin Xu	16163-013001 / AM100859	7387
1912	7590	06/15/2005	EXAMINER	
AMSTER, ROTHSTEIN & EBENSTEIN LLP 90 PARK AVENUE NEW YORK, NY 10016			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,718

Applicant(s)

XU ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Application

- [1] Claims 1-20 are pending in the application.
- [2] Receipt of an information disclosure statement, filed 2/3/2004, is acknowledged.
- [3] Applicant's preliminary amendment to the specification, filed 1/14/2004, is acknowledged.
- [4] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, and an amendment directing entry of the sequence listing into the specification, all filed 1/14/2004, is acknowledged.
- [5] The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Election/Restrictions

- [6] Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim(s) 1-2, drawn to a crystallized Kv channel-interacting protein 1 (KCHIP-1), classified in class 530, subclass 350.

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- II. Claim(s) 3-4, drawn to a crystallized Kv4.3 T1 domain (Kv4.3 T1), classified in class 530, subclass 350.
- III. Claim(s) 5-7, drawn to a three-dimensional model of KCHIP-1, classified in class 702, subclass 27.
- IV. Claim(s) 8-10, drawn to a three-dimensional model of Kv4.3 T1, classified in class 702, subclass 27.
- V. Claim(s) 11-14, drawn to a method for identifying an agent that interacts with KCHIP-1, classified in class 702, subclass 27.
- VI. Claim(s) 15-18, drawn to a method for identifying an agent that interacts with Kv4.3 T1, classified in class 702, subclass 27.
- VII. Claim(s) 19, drawn to an agent that interacts with KCHIP-1, broadly classified in class 514, subclass 789 as the structure and composition of the agent is undefined. See ¶ [0032] of the specification.
- VIII. Claim(s) 20, drawn to an agent that interacts with Kv4.3 T1, broadly classified in class 514, subclass 789 as the structure and composition of the agent is undefined. See ¶ [0032] of the specification.

[7] The inventions are distinct, each from the other because:

[8] The crystals of Groups I-II are distinct as each of the crystals comprises a structurally distinct polypeptide and each has different unit cell dimensions.

Further, the crystal of Group I or II would not render the other obvious to one of ordinary skill in the art.

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[9] The three-dimensional structures of Groups III-IV are distinct as each of structures has distinct structural coordinates generated from a structurally distinct crystal. Further, the three-dimensional structure of Group III or IV would not render the other obvious to one of ordinary skill in the art.

[10] The agents of Groups VII-VIII are distinct as each of the agents binds to a distinct polypeptide. Further, the agent of Group VII or VIII would not render the other obvious to one of ordinary skill in the art.

[11] The crystals of Groups I-II, the three-dimensional structures of Groups III-IV, and the agents of Groups VII-VIII are unrelated entities capable of separate manufacture, use, and effect. The three-dimensional structures of Groups III-IV can be made by means other than from the structural coordinates of the crystals of Groups I-II, such as being made by homology modeling.

[12] The crystals of Groups I-II are unrelated to the methods of Groups V-VI as they are neither made nor used by the methods of Groups V-VI.

[13] The three-dimensional structure of Group III and the method of Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the three-dimensional structure of Group III can be used for homology modeling and a method for identifying an agent that binds with KCHIP-1 can be practiced by employing a yeast two-hybrid assay.

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[14] The three-dimensional structure of Group III and the method of Group VI are unrelated as it is neither made nor used by the method of Group VI.

[15] The three-dimensional structure of Group IV and the method of Group V are unrelated as it is neither made nor used by the method of Group V.

[16] The three-dimensional structure of Group IV and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the three-dimensional structure of Group IV can be used for homology modeling and a method for identifying an agent that binds with Kv4.3 T1 can be practiced by employing a yeast two-hybrid assay.

[17] The methods of Groups V-VI are independent as they comprise different active method steps, utilize different products, and/or yield different results.

[18] The agent of Group VII and the method of Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agent of Group VII can be used as an affinity reagent for the purification of a KCHIP-1 polypeptide.

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[19] The agent of Group VII and the method of Group VI are unrelated as it is neither made nor used by the method of Group VI.

[20] The agent of Group VIII and the method of Group V are unrelated as it is neither made nor used by the method of Group V.

[21] The agent of Group VIII and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agent of Group VIII can be used as an affinity reagent for the purification of a Kv4.3 T1 polypeptide.

[22] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, the inventions of Groups I-VIII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. In view of the recited limitations of the claims of each invention, a separate patent and non-patent literature search for each of the inventions of Groups I-VIII is required. As such, co-examination of the inventions of Groups I-VIII would require a serious burden on the examiner.

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[23] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[24] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[25] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the

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rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

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for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER